UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA, Plaintiff, v. STEPHEN J. POINDEXTER, an individual, and PHARMACIST'S ULTIMATE HEALTH, a corporation, Defendants.

CIVIL NO. _____
12cv2814
DSD/AJB

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Stephen J. Poindexter, an individual, and Pharmacist's Ultimate Health, a corporation, from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

b. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate

commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

c. 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use;

d. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

e. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) & (c).

DEFENDANTS

4. Defendant Pharmacist's Ultimate Health ("PUH") is a privately-held Minnesota corporation that was founded in 1997. The firm has four full-time employees, and operates from its

headquarters located at 200 S. Owasso Boulevard East, Saint Paul, Minnesota. PUH sells products under the PUH brand and also the trade name "Doctor's Natural Therapy" ("DNT").

5. Defendant Stephen J. Poindexter is PUH's President, Senior Executive Vice President, Secretary, and Treasurer.

6. Defendants promote and distribute many products, including PUH allergy relief complex, DNT allergy relief complex, DNT lycopene standardized extract, DNT Co Q-10, DNT Cold & Flu Defense, DNT Cholesterol Homocysteine, DNT Prostate Companion, DNT Ginger Root Standardized Extract, and the DNT USP (Pharmaceutical Strength) Progesterone Cream.

7. Defendants use two different contract manufacturers to manufacture their products. Mary Ellen Products, located in Saint Paul, Minnesota, manufactures Defendants' Natural USP Progesterone Cream. Bactolac Pharmaceutical, Inc., ("Bactolac"), located in Hauppauge, New York, manufactures all of Defendants' other products.

8. Defendants operate two websites: www.puhcorp.com for PUH products, and www.doc-nt for DNT-brand products. Defendants are solely responsible for the content of these websites.

9. Defendants sell their products wholesale to pharmacies, health care professionals, and chiropractors through these websites and telephone orders.

DEFENDANTS' PRODUCTS ARE DRUGS UNDER THE ACT

10. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). Moreover, products (other than food) "intended to affect the structure or any function" of the human body are drugs within the meaning of 21 U.S.C. § 321(g)(1)(C).

11. The intended use of a product may be determined from any relevant source, including labeling. 21 C.F.R. § 201.128.

12. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment to the article is not necessary. See Kordel v. United States, 335 U.S. 345, 349-50 (1948).

13. Defendants promote their products for use as drugs on two websites, www.puhcorp.com and www.doc-nt.com. These websites are part of an integrated distribution scheme for Defendants' products because they each contain PUH's phone number and address from which customers can purchase Defendants' products. Defendants also promote their products through

brochures, which are available upon request, and on the labels that accompany each product.

14. Defendants' websites, product brochures, and labels make many drug claims about each product demonstrating that the products are to be used in the diagnosis, cure, mitigation, treatment, or prevention of numerous diseases, including cancer, hypertension, congestive heart failure, gastroesophageal reflux (GERD), and osteoporosis. For example, Defendants make the following claims:

a. PUH Allergy Relief Complex: "All-natural support for relief of allergy symptoms";

b. DNT Allergy Relief Complex: "All-natural support for symptomatic relief of allergy symptoms; Bromelain and Nettle Root each possess synergistic allergy relief properties";

c. DNT Lycopene Standardized Extract: "Use of Lycopene during episodes of prostate cancer has been associated with positive results; Lycopene is a unique flavonoid associated with significant risk reduction for prostate cancer";

d. DNT Co Q-10: "Modulate[s] peripheral neuropathy often found in patients with diabetes; Effects hypertension and congestive heart failure";

e. DNT Cold & Flu Defense: "Fight[s] cold and flu viruses while boosting the immune system . . . [e]nhanc[es] white blood cell production";

f. DNT Cholesterol Homocysteine: "Promotes normal cholesterol levels . . .";

g. DNT Prostate Companion: "All-natural Saw Palmetto [an ingredient] has been shown clinically to reduce the symptoms and clinical signs of benign prostate hypertrophy (BPH)";

h. DNT Ginger Root Standardized Extract: "Can reduce the symptoms of GERD"; and

i. DNT Progesterone Cream: "Helps prevent osteoporosis; For prevention of osteoporosis."

15. Based on these claims, and many others found on Defendants' websites, brochures and labels, these products and others promoted and distributed by Defendants are drugs under the Act.

16. Defendants' progesterone cream is also a drug by regulation. See 21 C.F.R. § 310.530.

DEFENDANTS DISTRIBUTE PRODUCTS THAT ARE UNAPPROVED NEW DRUGS

17. Under the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 355(a), (b), (i), and (j).

18. A "new drug" is defined as any drug "the composition of which is such that the drug is not generally recognized,

among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/GRAE"), it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d). If it is an over-the-counter ("OTC") drug, the product must comply with a monograph established pursuant to an FDA regulation. 21 C.F.R. § 330.1.

19. The introduction or delivery for introduction into interstate commerce of an unapproved new drug violates the Act. 21 U.S.C. § 331(d).

20. Defendants' drugs are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

21. Because Defendants' progesterone cream contains a topically-applied hormone, it cannot be generally recognized as safe and effective for its intended use. See 21 C.F.R. § 310.530.

22. FDA has searched its records for NDA, ANDA, and IND submissions by Defendants. Defendants have no such approvals on file from FDA. Moreover, Defendants' drugs do not conform to the OTC monograph set forth in 21 C.F.R. § 330.1, or any other OTC drug monograph. As a result, Defendants' drugs may not be distributed legally in interstate commerce.

DEFENDANTS' PRODUCTS ARE MISBRANDED DRUGS

23. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

24. A drug is misbranded if its label fails to bear "adequate directions for use" as defined by 21 C.F.R. § 201.5(a), and it does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1).

25. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a)

26. Defendants' drug products are misbranded under 21 U.S.C. § 352(f)(1) because they lack adequate and well-controlled studies to support the claims made for them. Their labeling therefore necessarily fails to bear adequate directions for use, and, because they are unapproved new drugs, they are not exempt from that requirement. 21 C.F.R. §§ 201.100(c)(2), 201.115.

27. Some of Defendants' drug products are also prescription drugs because of the purposes for which they are intended, including the self-diagnosis and treatment of, among other diseases, cancer, hypertension, congestive heart failure, GERD, and osteoporosis, and the "collateral measures necessary to [their] use." 21 U.S.C. § 353(b)(1)(A). By definition, prescription drugs cannot contain adequate directions for lay use, see id., causing Defendants' prescription drug products to be misbranded under 21 U.S.C. § 352(f)(1).

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

28. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." Id. Dietary supplements are deemed to be "food" under the Act, except for purposes of 21 U.S.C. §§ 321(g) and 350f. Id.

29. Defendants' products are labeled as dietary supplements on their principal display panels, as defined in 21 C.F.R. § 101.1. Furthermore, each of Defendants' drugs contain at least one of the dietary ingredients specified in 21 U.S.C. § 321(ff).

30. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice for dietary supplements ("Dietary Supplement cGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to Dietary Supplement cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a quality finished product. Dietary supplements not manufactured, prepared, packed, or held in conformance with Dietary Supplement cGMP are deemed to be adulterated. 21 U.S.C. § 342(g)(1). The Dietary Supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

31. FDA's February 15 - March 12, 2012 inspection of Defendants' facility (the "March 2012 inspection") establishes that the dietary supplements that Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they were prepared, packed, and held in a manner that does not conform to Dietary Supplement cGMP. Defendants' significant deviations from Dietary Supplement cGMP, include, but are not limited to, the following:

a. Failure to prepare a written master manufacturing record for each unique dietary supplement formulation, as required by 21 C.F.R. § 111.205. Defendants do not provide their contract manufacturers with any master manufacturing records (other than the product labels). This practice is insufficient to ensure quality and batch-to-batch uniformity of the dietary supplements;

b. Failure to establish packaging and labeling specifications for finished dietary supplements, where control is necessary to ensure the packaging and labeling operations meet the requirements of the master manufacturing record, as required by 21 C.F.R. §§ 111.70 and 111.415. Defendants provide their contract manufacturers with labels; however, they do not include any packaging or labeling specifications. This practice is insufficient to ensure that the dietary supplements are uniformly packaged and labeled accordingly to specifications, which should be contained in a master manufacturing record;

c. Failure to establish and follow written procedures that specify responsibilities for quality control, as required by 21 C.F.R. § 111.103. During the inspection, FDA investigators requested quality control documents from Defendants. The only document Defendants produced was entitled "Returns and Exchanges," which explains only how customers can

return or exchange product. Defendants did not produce any other quality control documents; and

d. Failure to establish and follow written procedures to review and investigate product complaints, as required by 21 C.F.R. § 111.553. Specifically, Defendants do not have any written procedures for reviewing and investigating product complaints.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

32. During the March 2012 inspection, FDA investigators documented the shipment of Defendants' products from their headquarters in St. Paul, Minnesota to customers located in Florida, Texas, California, New York, Michigan, and Mississippi, among others. Such shipments constitute the introduction or delivery for introduction into interstate commerce within the meaning of 21 U.S.C. §§ 331(a) and (d).

33. Defendants' conduct also satisfies the interstate commerce element under 21 U.S.C. § 331(k), because, prior to distribution, Defendants receive all but one of their finished drug and dietary supplement products from outside Minnesota. Plaintiff is not asserting that Defendants violate 21 U.S.C. § 331(k) for the one product that is manufactured and distributed in Minnesota.

HISTORY

34. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

35. FDA first inspected Defendants' facility in April 2010, after which FDA explained to Defendants that some of their products contained active pharmaceutical ingredients that caused their products to be drugs, even though Defendants labeled them as dietary supplements.

36. Based on the April 2010 inspection, and a subsequent review of Defendants' websites in August 2011, FDA issued Defendants a Warning Letter dated August 22, 2011. The Warning Letter identified four different products marketed and distributed by Defendants that, based on their labeling, were unapproved new drugs under the Act. The Warning Letter instructed Defendants that, under 21 U.S.C. § 331(d), continued distribution of these products was prohibited. The Warning Letter also warned Defendants that continued violations could result in further regulatory action including seizure and/or injunction.

37. Defendants did not respond to FDA's Warning Letter until February 21, 2012 — 6 days after FDA initiated its February-March 2012 ("March 2012") inspection. At the start of the March 2012 inspection, Defendant Poindexter informed the FDA

investigator that he had removed the four products specifically-named in the Warning Letter from Defendants' websites. However, in a letter dated February 21, 2012, Defendants stated to FDA that they did not consider their products to be drugs, and that they would continue to market three of the four products identified in the Warning Letter. Defendants confirmed that they had stopped distributing the fourth product.

38. At the close of the March 2012 inspection, FDA investigators met with Defendant Poindexter and presented him with a List of Inspectional Observations ("FDA Form 483"). At that time, the FDA investigators also informed Defendant Poindexter that Defendants violate the Dietary Supplement cGMP regulations.

39. Defendants' history of promoting products to cure, mitigate, treat, prevent, and/or reduce the risk of diseases including, but not limited to, cancer, hypertension, congestive heart failure, GERD, and osteoporosis, demonstrates their unwillingness to comply with the Act. Based on Defendants' most recent course of conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (k), and (d).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors,

officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d), by distributing unapproved new drugs in interstate commerce;

B. Violating 21 U.S.C. § 331(a), by distributing misbranded drugs in interstate commerce;

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded;

D. Violating 21 U.S.C. § 331(a), by distributing adulterated dietary supplements in interstate commerce; and

E. Violating 21 U.S.C. § 331(k), by causing dietary supplements that Defendants hold for sale after shipment interstate commerce to become adulterated;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from promoting and distributing any drug or dietary supplement unless and until:

A. An approved new drug application or abbreviated new drug application pursuant to 21 U.S.C. § 355(a) or (j) is in effect for the product; or

B. An investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. Defendants have removed all claims that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g), including from: (1) each of their product labels, labeling, and promotional materials; (2) websites owned or controlled by or related to Defendants; (3) any other media; and (4) from any and all dietary supplement or cosmetic products under Defendants' custody, possession, or control;

III. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing dietary supplements, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold dietary supplements are established, operated, and administered in conformity with Dietary Supplement cGMP and the Act, in a manner that has been found acceptable by FDA;

IV. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug or dietary supplement to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

V. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 5th day of November, 2012

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